

# Institutional Biosafety Committee (IBC)

## Meeting Minutes

| <b>Institution:</b>           | <b>Wake Forest University School of Medicine</b> |   |   |  |
|-------------------------------|--|---|---|--|
| <b>Meeting Date and Time:</b> | October 15 <sup>th</sup> 2025                    |   |   |  |
| <b>Meeting Type:</b>          | Online via Microsoft Teams                       |   |   |  |
|                               | Name   | Role and Department   | Attendance                                  |  |
| <b>IBC Members Present:</b>   | Frank Marini, PhD                                | IBC Chair, WFIRM  | <input checked="" type="checkbox"/> Present | <input type="checkbox"/> Absent            |
|                               | Anthony Blaeser, PhD                             | IBC Vice Chair<br>Musculoskeletal<br>Department                         | <input checked="" type="checkbox"/> Present | <input type="checkbox"/> Absent            |
|                               | Samuel Centanni, PhD                             | Voting Member,<br>Translational Neuroscience                            | <input checked="" type="checkbox"/> Present | <input type="checkbox"/> Absent            |
|                               | Ji Hyun Kim, PhD                                 | Voting Member, WFIRM  | <input type="checkbox"/> Present            | <input checked="" type="checkbox"/> Absent |
|                               | Elizabeth Palavecino, MD                         | Voting Member, Pathology  | <input checked="" type="checkbox"/> Present | <input type="checkbox"/> Absent            |
|                               | David Ornelles, PhD                              | Voting Member,<br>Microbiology and<br>Immunology                        | <input type="checkbox"/> Present            | <input checked="" type="checkbox"/> Absent |
|                               | Marlena Westcott, PhD                            | Voting Member,<br>Microbiology and<br>Immunology                        | <input checked="" type="checkbox"/> Present | <input type="checkbox"/> Absent            |
|                               | Brian Strittmatter, PharmD,<br>MSCR              | Voting Member, Pharmacy<br>Clinical Trial Services,<br>Pharmacy Manager | <input checked="" type="checkbox"/> Present | <input type="checkbox"/> Absent            |
|                               | Patrick McNutt, PhD                              | Voting Member, WFIRM,   | <input checked="" type="checkbox"/> Present | <input type="checkbox"/> Absent            |
|                               | Linda Metheny-Barlow, PhD                        | Voting Member, Radiation<br>Oncology                                    | <input type="checkbox"/> Present            | <input checked="" type="checkbox"/> Absent |
|                               | Swapn Das, PhD, MSc                              | Voting Member, IM.<br>Endocrinology &<br>Metabolism                     | <input type="checkbox"/> Present            | <input checked="" type="checkbox"/> Absent |
|                               | Caryn Gee Morse, MD, PhD                         | Voting Member, IM,<br>Infectious Diseases                               | <input type="checkbox"/> Present            | <input checked="" type="checkbox"/> Absent |
|                               | Drew Kiraly, MD                                  | Voting Member,<br>Translational Neuroscience                            | <input type="checkbox"/> Present            | <input checked="" type="checkbox"/> Absent |
|                               | Robert Hampson, PhD                              | Voting Member, WFIRM  | <input type="checkbox"/> Present            | <input checked="" type="checkbox"/> Absent |
|                               | Farah Mougeot, PhD, MS                           | Voting Member,<br>Translational Research –<br>Oral Medicine             | <input type="checkbox"/> Present            | <input checked="" type="checkbox"/> Absent |
|                               | Kimberly Woodward, MD,<br>MPH                    | Voting Member, Pathology  | <input checked="" type="checkbox"/> Present | <input type="checkbox"/> Absent            |
|                               | Paris Charilaou, MD, FACP                        | Voting Member,<br>Gastroenterology and<br>Hepatology                    | <input checked="" type="checkbox"/> Present | <input type="checkbox"/> Absent            |

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|   | Yuming Jiang, MD, PhD   | Voting Member, Radiation Oncology                 | <input type="checkbox"/> Present            | <input checked="" type="checkbox"/> Absent |
|   | Dan Hurley  | Local Non-Affiliated Community Member (Charlotte) | <input checked="" type="checkbox"/> Present | <input type="checkbox"/> Absent            |
|   | Jeanette Bennett  | Community Member (Charlotte)                      | <input type="checkbox"/> Present            | <input checked="" type="checkbox"/> Absent |
|   | Kara Milton   | Community Member (Winston Salem)                  | <input type="checkbox"/> Present            | <input checked="" type="checkbox"/> Absent |
|   | Adam Bray   | Community Member (Winston Salem)                  | <input checked="" type="checkbox"/> Present | <input type="checkbox"/> Absent            |
|   | Christpher Ohl, MD  | Voting Member, IM, Infectious Diseases (Ad-Hoc)   | <input type="checkbox"/> Present            | <input checked="" type="checkbox"/> Absent |
|   | Scott Gamble, DVM   | Voting Member, Animal Expert                      | <input checked="" type="checkbox"/> Present | <input type="checkbox"/> Absent            |
|   | Lisa Colvin   | Voting Contact, IBC Administrator                 | <input checked="" type="checkbox"/> Present | <input type="checkbox"/> Absent            |
|   | Emylee Pedersen   | Voting Contact, IBC Administrator                 | <input checked="" type="checkbox"/> Present | <input type="checkbox"/> Absent            |
|   | Bernadette Menuey   | Voting Member, Biosafety Officer                  | <input checked="" type="checkbox"/> Present | <input type="checkbox"/> Absent            |
|   | Jessica Baker   | Voting Member, IACUC Representative               | <input checked="" type="checkbox"/> Present | <input type="checkbox"/> Absent            |
|   | Katy Heide  | Voting Member, EHS, Environmental Compliance      | <input checked="" type="checkbox"/> Present | <input type="checkbox"/> Absent            |
|   | Ex Officio W/O Vote   |   |   |  |
|   | Suzy Mounsey  | Animal Resources Program                          | <input type="checkbox"/> Present            | <input checked="" type="checkbox"/> Absent |
|   | Gaye Hodges   | Animal Resources Program                          | <input checked="" type="checkbox"/> Present | <input type="checkbox"/> Absent            |
|   | Stephen Fisenne   | WFU Representative                                | <input checked="" type="checkbox"/> Present | <input type="checkbox"/> Absent            |
|   | Morgan Lawson   | Environmental Health & Safety                     | <input checked="" type="checkbox"/> Present | <input type="checkbox"/> Absent            |
|   | Jennifer Williams   | Environmental Health & Safety                     | <input checked="" type="checkbox"/> Present | <input type="checkbox"/> Absent            |
|   | Paul Haliburton   | EHS, AVP  | <input type="checkbox"/> Present            | <input checked="" type="checkbox"/> Absent |
|   | Joseph Kim  | AHWFB Teammate Health                             | <input type="checkbox"/> Present            | <input checked="" type="checkbox"/> Absent |
| Quorum:   | Yes   |   |   |  |
| Call to Order:                                    | Dr. Marini called meeting to order at 12:46   |   |   |  |
| Conflicts of Interest:                            | Chair reminded all members present to identify any conflicts of interest as protocols are reviewed. No COIs to disclose for this meeting. |   |   |  |
| Review and Approval of Previous Meeting Minutes:  | Motion to approve by Dr. Marini, second by Dr. McNutt.  |   |   |  |
| Review of Prior Meeting Business (if applicable): | NA  |   |   |  |
| New IBC Protocol                                  |   |   |   |  |

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| <b>PI Name:</b>   | Shelbi Atrash  |
| <b>Registration Number:</b>   | B25-CT-C-008   |
| <b>IBC Registration Title:</b>  | D8310C00001: Phase Ib/II Study of AZD0120, Dual-Targeting Autologous Chimeric Antigen Receptor T-cell (CAR T) Therapy Directed Against CD19 and B-cell Maturation Antigen (BCMA) in Participants With Relapsed/Refractory Multiple Myeloma (DURGA-1) (NCT05850234)   |
| <b>Project Overview:</b>  | Clinical trial aiming to evaluate the safety and efficacy of AZD0120 for treating patients with relapsed/refractory multiple myeloma. In the Phase Ib part of the study, the safety of different doses of AZD0120 will be evaluated. In the Phase II part of the study, efficacy of the selected RP2D of AZD0120 will be further evaluated, as will the continued safety evaluation of the product |
| <b>Applicable NIH Guidelines:</b>   | Section III-C-1  |
| <b>Agent Description:</b><br>e.g. virulence,<br>pathogenicity,<br>environmental stability               | GC012F (AZD0120), is composed of [REDACTED]  |
| <b>Types of Manipulations:</b>  | Manipulations performed by manufacturer of study agent.  |
| <b>Source of nucleic (DNA/RNA) sequences:</b><br>e.g. species   | N/A  |
| <b>Nature of nucleic acid sequences:</b><br>e.g. structural gene,<br>oncogene                           | DNA Coding for [REDACTED] to target and kill cancer cells.   |
| <b>Host(s) and Vector(s):</b>   | Host: Patient-derived T-Cells<br>[REDACTED]  |
| <b>Will a transgene be expressed? If so, what is the function of the protein that will be produced?</b> | [REDACTED]   |
| <b>Risk Assessment Discussion Points:</b>   | None   |
| <b>Training:</b>  | Training provided by study sponsor.  |
| <b>Occupational Health Review (if applicable):</b>  | None   |
| <b>Biosafety Level:<br/>Animal Biosafety Level:</b>   | BSL 2  |
| <b>IBC Vote:</b>  | Approve at BSL 2   |
| <b>New IBC Protocol</b>   |  |
| <b>PI Name:</b>   | Shih-Ying Wu   |

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| <b>Registration Number:</b>   | B25-W-013   |
| <b>IBC Registration Title:</b>  | Mechanism of brain and leptomeningeal metastasis  |
| <b>Project Overview:</b>  | TBD   |
| <b>Applicable NIH Guidelines:</b>   | TBD   |
| <b>Agent Description:</b><br>e.g. virulence,<br>pathogenicity,<br>environmental stability               | TBD   |
| <b>Types of Manipulations:</b>  | TBD   |
| <b>Source of nucleic (DNA/RNA) sequences:</b><br>e.g. species   | TBD   |
| <b>Nature of nucleic acid sequences:</b><br>e.g. structural gene,<br>oncogene                           | TBD   |
| <b>Host(s) and Vector(s):</b>   | TBD   |
| <b>Will a transgene be expressed? If so, what is the function of the protein that will be produced?</b> | TBD   |
| <b>Risk Assessment Discussion Points:</b>   | Unclear what work is being conducted. Protocol requires revision to clarify recombinant DNA work to be done. Administrators to schedule a meeting with study team to discuss protocol concerns and provide guidance on completing the protocol. |
| <b>Training:</b>  | Initial Biosafety Training<br>Annual Biosafety Retraining<br>Animal Biosafety<br>NIH Recombinant DNA Guidelines<br>Emergency and Incident Response to Biohazard Spills and Releases   |
| <b>Occupational Health Review (if applicable):</b>  | TBD   |
| <b>Biosafety Level:<br/>Animal Biosafety Level:</b>   | TBD   |
| <b>IBC Vote:</b>  | Tabled  |
| <b>New IBC Registrations and Amendments for Review</b>  |   |
| <b>PI Name:</b>   | Chris Peters  |
| <b>Registration Number:</b>   | B25-W-015   |

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| <b>IBC Registration Title:</b>  | Mechanisms of sensory neuron plasticity in bone and joints   |
| <b>Project Overview:</b>  | <p>Transgenic mouse lines in combination with viral vector-based gene targeting to visualize and quantify the distribution and density of sensory neuron subsets in whole mouse bone/joint tissue including tumor bearing and arthritic mice. We will also interrogate the functional role of [REDACTED]</p> <p>Importance: These experiments will examine for the first time the functional role [REDACTED]</p> |
| <b>Applicable NIH Guidelines:</b>   | Section III-D-4  |
| <b>Agent Description:</b><br>e.g. virulence, pathogenicity, environmental stability                     | [REDACTED] Gene inserts conducted by vendor.   |
| <b>Types of Manipulations:</b>  | Manipulations conducted by manufacturer.   |
| <b>Source of nucleic (DNA/RNA) sequences:</b><br>e.g. species   | DNA/RNA sourced from approved vendor.  |
| <b>Nature of nucleic acid sequences:</b><br>e.g. structural gene, oncogene                              | Protein-coding gene  |
| <b>Host(s) and Vector(s):</b>   | <p>Hosts:<br/>5HT3R-Flpo mouse (Htr3atm1.1(flpo)Rudy/J, Strain #030755)<br/>TRPV1-Cre mouse (B6.129-Trpv1tm1(cre)Bbm/J, Strain #017769)</p> <p>Vectors:<br/>[REDACTED]</p>   |
| <b>Will a transgene be expressed? If so, what is the function of the protein that will be produced?</b> | Cell Fluorescence<br>[REDACTED]  |
| <b>Risk Assessment Discussion Points:</b>   | None   |
| <b>Training:</b>  | <p>Initial Biosafety Training</p> <p>Annual Biosafety Retraining</p> <p>Animal Biosafety</p> <p>NIH Recombinant DNA Guidelines</p> <p>Emergency and Incident Response to Biohazard Spills and Releases</p>   |

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| <b>Occupational Health Review (if applicable):</b>  | None   |
| <b>Biosafety Level:<br/>Animal Biosafety Level:</b>   | BSL 1/ABSL 1   |
| <b>IBC Vote:</b>  | Approve at BSL/ABSL 1  |
| <b>New IBC Protocol</b>   |  |
| <b>PI Name:</b>   | Cleary/McNutt  |
| <b>Registration Number:</b>   | B25-W-006  |
| <b>IBC Registration Title:</b>  | Characterizing BSL3 arboviruses in human organoids   |
| <b>Project Overview:</b>  | Brain organoids will be exposed to vehicle or clinical isolates of [REDACTED] and evaluated for cellular and molecular changes in response to infection. |
| <b>Applicable NIH Guidelines:</b>   | N/A  |
| <b>Agent Description:</b><br>e.g. virulence,<br>pathogenicity,<br>environmental stability               | N/A  |
| <b>Types of Manipulations:</b>  | N/A  |
| <b>Source of nucleic (DNA/RNA) sequences:</b><br>e.g. species   | N/A  |
| <b>Nature of nucleic acid sequences:</b><br>e.g. structural gene,<br>oncogene                           | N/A  |
| <b>Host(s) and Vector(s):</b>   | N/A  |
| <b>Will a transgene be expressed? If so, what is the function of the protein that will be produced?</b> | N/A  |
| <b>Risk Assessment Discussion Points:</b>   | N/A  |
| <b>Training:</b>  | BSL 3 Facilities/Safety Training   |
| <b>Occupational Health Review (if applicable):</b>  | TBD  |
| <b>Biosafety Level:<br/>Animal Biosafety Level:</b>   | TBD  |
| <b>IBC Vote:</b>  | TBD  |

| Resubmission  |   |
|---|---|
| <b>PI Name:</b>   | Brennan   |
| <b>Registration Number:</b>   | B25-CT-C-009  |
| <b>IBC Registration Title:</b>  | A Randomized, Double-Blind, Placebo-Controlled Study to Determine the Efficacy and Safety of AAV2-hAQP1 Gene Therapy in Participants with Radiation-Induced Late Xerostomia MGT-AQP1-201  |
| <b>Project Overview:</b>  | AAV2-hAQP1 [REDACTED] is a [REDACTED] adults with ionizing radiation (IR)-induced xerostomia and salivary gland hypofunction. It is anticipated that [REDACTED] improve xerostomia symptoms. AAV2-hAQP1 is administered as a one-time treatment (unilateral or bilateral single dose administration) directly to the parotid gland(s) via cannulation of Stensen's duct |
| <b>Applicable NIH Guidelines:</b>   | Section III-C-1   |
| <b>Agent Description:</b><br>e.g. virulence, pathogenicity, environmental stability                     | AAV2-hAQP1 ([REDACTED]) is a [REDACTED] adults with ionizing radiation (IR)-induced xerostomia and salivary gland hypofunction.   |
| <b>Types of Manipulations:</b>  | Manipulations performed by manufacturer of study agent.   |
| <b>Source of nucleic (DNA/RNA) sequences:</b><br>e.g. species   | [REDACTED]  |
| <b>Nature of nucleic acid sequences:</b><br>e.g. structural gene, oncogene                              | Protein-coding gene   |
| <b>Host(s) and Vector(s):</b>   | Host: patient parotid epithelial cells<br>Vector: AAV2-hAQP1  |
| <b>Will a transgene be expressed? If so, what is the function of the protein that will be produced?</b> | Water channel, facilitating rapid water transport across cell membranes   |
| <b>Risk Assessment Discussion Points:</b>   | None  |
| <b>Training:</b>  | Training provided by study sponsor.   |
| <b>Occupational Health Review (if applicable):</b>  | None  |
| <b>Biosafety Level:</b><br><b>Animal Biosafety Level:</b>   | BSL 2   |
| <b>IBC Vote:</b>  | Approve at BSL 2  |

| Modification             |  |                                     |
|--------------------------|--|-------------------------------------|
| PI Name:                 | Druhan, L  |                                     |
| Registration Number:     | 01-24-01   |                                     |
| IBC Registration Title:  | Immunotherapy in Hematological Malignancies        |                                     |
| Summary of Changes       | Addition of HSPC-NK Cells                          |                                     |
| IBC Vote                 | Approve Modification, Biosafety level remains at 2 |                                     |
| Post-Approval Monitoring |  |                                     |
| PI                       | Protocol Number                                    | PAM Date/Outcome                    |
| X. Ma                    | 05.2015.Ortho.010000.644.01D                       | 10/2025/ No changes                 |
| J. Sanders               | 09.2024.InfDis.010000.683.17                       | 10/2025                             |
| J. Sanders               | 08.2024.InfsDis.110000.683.13                      | 10/2025                             |
| J. Willey                | 09.2024.RadOnc.110000.786.01                       | 10/2025/ No Changes                 |
| J. Weiner                | 09.2019.105000.1100000.238.01C                     | 10/2025<br>Awaiting Resubmission    |
| J. Huo                   | (10-22-01)   | 10/25/2025<br>Awaiting Resubmission |
| R. Garcia                | (10-24-02)   | 10/2025                             |
| Other                    |  |                                     |
| New Business:            | None   |                                     |
| Review of Incidents:     | None   |                                     |
| Lab Assessments Update:  | N/A  |                                     |
| IBC Training:            | N/A  |                                     |
| Public Comments:         | None   |                                     |
| Adjournment:             | Meeting adjourned at 1:20                          |                                     |